

REMARKS

Applicants thank the Examiner for the very thorough consideration given the present application. Claims 1, 3-8, 10-12, 14-19 and 21-22 are currently pending in this application. No new matter has been added by way of the present amendment. For instance, the amendments to claims 1 and 12 are supported by the Specification as originally filed at, for example, page 8, lines 17-25. Accordingly, no new matter has been added.

At the outset, the present application is believed to be in condition for allowance. Entry of this amendment is requested under 37 C.F.R. §1.116, as the amendment raises no new issues which would require further search and/or consideration by the Examiner. Alternatively, Applicant requests entry of the amendment in order to place the claims in better form for consideration on Appeal.

In view of the amendments and remarks herein, Applicants respectfully request that the Examiner withdraw all outstanding rejections and allow the currently pending claims.

Issues Under 35 U.S.C. 103(a)

Claims 1, 3-8, 11, 12, 14-19 and 22 stand rejected under 35 U.S.C. 103(a) as being obvious over Norton (U.S. 6,989,100) (hereinafter “Norton”) in view of Klee et al. (U.S. 6,493,639) (hereinafter “Klee”). Additionally, claims 10 and 21 stand rejected as being obvious over Norton in view of Klee and further in view of Teschemacher et al. (U.S. 4,681,871) (hereinafter “Teschemacher”). Applicants respectfully traverse.

Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, the Examiner must make the factual determinations set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). “[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability.” *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). A patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. *KSR Int'l Co. v Teleflex Inc.*, 82 USPQ 2d 1385 (U.S. 2007). There must be a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. *Id.* The Supreme Court of the United States has recently held that the “teaching, suggestion, motivation test” is a valid test for obviousness, albeit one which cannot be too rigidly applied. *Id.* “[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *Id.* (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)).

The present invention is directed, *inter alia*, to a sample analyzing method, which comprises:

- (a) adding at least one reference material to each of multiple samples;
- (b) obtaining three-dimensional data as a result of **liquid** chromatography mass spectrometry for the multiple samples, wherein the three-dimensional data comprises a parameter indicating a mass-to-charge ratio, a parameter indicating ionic intensity, and a parameter indicating a retention time;

- (c) correcting the parameter indicating a retention time in the three-dimensional data for the multiple samples using at least one peak of the at least one reference material;
- (d) comparing the corrected data obtained in said step (c) for the multiple samples to analyze differences among the multiple samples; and
- (e) outputting a result of the comparison in step (d) (emphasis added) (see, e.g., claim 1).

Moreover, the present invention is directed to a computer-readable medium on which is embodied a sample analyzing program comprising instructions which, when executed, cause a computer to execute:

- a procedure (a) of inputting three-dimensional data obtained as a result of liquid chromatography mass spectrometry for multiple samples to each of which at least one reference material has been added, wherein the three-dimensional data comprises a parameter indicating a mass-to-charge ratio, a parameter indicating ionic intensity, and a parameter indicating a retention time;
- a procedure (b) of correcting the parameter indicating a retention time in the three-dimensional data for the multiple samples using at least one peak of the reference material; and
- a procedure (c) of comparing the data corrected in said procedure (b) for the multiple samples to analyze differences among the multiple samples; and
- a procedure (d) of outputting a result of the comparison in said procedure (c) (see, e.g., claim 12) (emphasis added).

Applicants respectfully submit that the cited references fail to teach or suggest a sample analyzing method or computer-readable medium as claimed.

The Examiner argues that Norton discloses a sample analyzing method, which comprises using multiple samples which contain at least one material which may be used as a reference. Applicants respectfully disagree. As previously discussed, Norton fails to disclose a reference material being added to each of the multiple samples on which liquid chromatography mass spectrometry is performed, as required by the claims.

The Examiner's attention is respectfully directed to col. 4, lines 35-50 of Norton, where this reference discloses:

*“...a time-aligning algorithm is applied to one or more pair of data sets. One data set can be chosen...to serve as a **reference spectrum** and all other data sets time-aligned to this spectrum...”* (emphasis added)

Norton does not teach or suggest a method which comprises using multiple samples which contain at least one material which may be used as a reference.

Moreover, Applicants submit that none of the passages cited by the Examiner teach or suggest a step of correcting the parameter indicating a retention time in the three-dimensional data for the multiple samples using at least one peak of the at least one reference material (e.g., claimed step (c) in claim 1; see also claimed procedure (b) in claim 12). The secondary references cited by the Examiner fail to cure the deficiencies of Norton.

Klee fails to teach or suggest a sample analyzing method or computer-readable medium as claimed, characterized in that internal standards are added to samples to obtain reference peaks or patterns.

Moreover, Klee teaches away from the present invention, as Klee has a negative perception with regard to adding internal standards to gas chromatography samples to correct the retention time (see, for example, col. 1, lines 55-63 of Klee, where this reference discloses that post-analysis mathematical approaches using reference peaks or patterns may lead to errors).

Thus, the cited references, alone or in combination, fail to teach or suggest a sample analyzing method or computer-readable medium as claimed. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

Conclusion

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and objections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Vanessa Perez-Ramos, Reg. No. 61,158 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

Application No. 10/551,148
Reply to Office Action of October 14, 2009

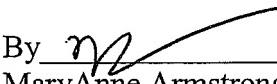
Attorney Docket No. 1254-0294PUS1

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

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